

### REMARKS/ARGUMENTS

Claims 1-3 and 6-11 are now pending, a total of 9 claims. Claims 1 and 9 are independent. Claims 11 is objected to because of the spelling of “lure” in line 2. Claims 1-3 and 6-11 have been rejected under 35 U.S.C. § 103(a).

Applicant respectfully requests reconsideration of the application.

The informalities objected to have been corrected. The spelling of “luer” in line 2 has been changed to “lure.”

#### I. Claims 1, 3 and 6-10

Claims 1,3 and 6-10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136) in view of Ito (U.S. 5,063, 025). As shown below, claims 1,3 and 6-10 are not anticipated, taught, or suggested by any of the cited references.

Independent claims 1 and 9 are reproduced below.

**Claim 1:** A pre-filled syringe, the syringe comprising a barrel pre-filled with a liquid, and a gasket,

wherein a peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant, and wherein one or both of the peripheral side surface that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with a polyethylene resin.

**Claim 9:** A pre-filled syringe, the syringe comprising a barrel pre-filled with a liquid, and a gasket,

wherein a surface of the gasket that is in contact with the liquid is laminated with a polyethylene resin, and wherein a peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a first tapered slant, and a second tapered slant is formed between the peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel and the restriction.

The Examiner has identified no suggestion or motivation to modify the Trull et al. reference, or to combine Trull et al. with Ito. MPEP § 2143. The Examiner has acknowledged that the Trull et al. device differs from the claimed invention in at least the respect that there is no disclosure of a surface of the gasket having a polyethylene resin as a laminate. The Examiner cites Ito as disclosing that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene or polypropylene (TEFLON). The Examiner further states, without a reference to Trull et al., Ito or any other factual support, that such material “eliminates the need for a lubricant.” (02/23/2004 Office Action, at 3.) Such a naked observation is insufficient to supply the required suggestion to combine the teachings of the cited references. *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998); MPEP § 2144.03.

In addition, Trull et al. teaches away from the need for lubrication of the gasket itself. Trull et al. relates to power-driven angiographic syringes and discloses that the plunger is operatively positioned within the syringe barrel by a power-assisted driving mechanism.

(Column 3, lines 57-59.) Retraction of the plunger is to be avoided except by Trull et al.'s power-driven mechanism. (Column 2, lines 6-32.)

Trull et al. is directed to a different underlying problem than the Ito reference. Ito is directed to a "linear plunger made of superelastic wire" (column 3, line 32-34, and claims 1-8.) The plunger of Ito is used in microsyringes containing non-oxidizable acids, such as hydrochloric acid or sulfuric acid, or other substances that can destroy or corrode the plunger surface. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992); *In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992); MPEP § 2144.03.

The protective coating layer of the Ito plunger prevents corrosion of the plunger surfaces. (Column 4, lines 44-53.) Plunger corrosion is not a problem addressed by the plunger of the angiographic syringe system in Trull et al. The Trull et al. plunger is designed for effective engagement and disengagement of a power driving mechanism. (Column 3, lines 57-59.)

Further, the purpose of Ito's microsyringe is to inject "precisely a minute amount" of a gaseous or liquid sample into an analytical apparatus. (Column 1, line 41.) Such use suggests a different problem to be solved than that of the high-viscosity contrast medium that may be used in the pre-filled syringe of the present invention.

Claims 1, 3 and 6-10 are patentable over the combination of Trull et al. and Ito.

## **II. Dependent Claim 2**

Claim 2 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al., as modified by Ito, and in further view of Akaike et al. (U.S. 5,061,247).

The Examiner cites Akaike et al. as disclosing that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. However, the Examiner can point to no specific teaching or suggestion to motivate the combination of three references -- Akaike et al., Trull et al. and Ito. MPEP § 2144.03. Thus, dependent claim 2 is patentable with independent claim 1, as discussed above, and recites further limitations that are patentable over the combination of Trull et al., Ito and Akaike et al.

## **III. Dependent Claim 11**

Claim 11 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al., as modified by Ito, and in further view of Higashikawa (U.S. 5,830,193).

The Examiner has acknowledged that the Trull et al. reference includes no disclosure of the syringe including a lure lock. Nor does Ito disclose a lure locking mechanism. The Examiner cites Higashikawa for disclosure of a lure lock, but identifies nothing in Trull et al. or Ito that suggests modifying the syringes to allow for needle mounting using the lure lock of Higashikawa.

Dependent claim 11 is patentable with independent claims 1 and 9, as discussed above, and recites further limitations that are patentable over the combination of Trull et al., Ito and Higashikawa.

In view of the foregoing, Applicant respectfully submits that the claims currently presented are in condition for allowance.

The Examiner is urged to telephone Applicant's undersigned counsel at the number noted below if it will advance the prosecution of this application, or with any suggestion to resolve any condition that would impede allowance.

Enclosed herewith is a Petition for Extension of Time for one (1) month.

Respectfully submitted,

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